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Nagasaki University (Japan)

neopharma Japan Co., Ltd.

Report on Results of Clinical Study on Using 5-Aminolevulinic Acid for patients with COVID-19

National University Corporation, Nagasaki University*¹ (represented by Shigeru Kono : hereinafter referred to as ‘Nagasaki University’), in association with neopharma Japan Co., Ltd.*² (represented by Hiroyuki Ishikawa : hereinafter referred to as ‘NPJ’), announced the results of a clinical study on the usage of 5-aminolevulinic acid*³ (hereinafter referred to as ‘5-ALA’) research, developed and manufactured by NPJ, and sodium ferrous citrate (hereinafter referred to as ‘SFC’), to treat patients with novel coronavirus infections (hereinafter referred to as ‘COVID-19’). These results demonstrated that, following a 14-day long administration of 5-ALA/SFC to patients with mild-to-moderate COVID-19 infections, the 5-ALA-SFC group did not show any significant differences in SARS-CoV-2 viral load or clinical symptom scores when compared with the control group. However, the 5-ALA/SFC administration group did show a noticeable trend towards ameliorating some symptoms experienced by patients.

This research was accepted for publication in the international journal ‘*Medicine*’ on August 1st, 2023 (JST) and published on August 25th, 2023.

[URL]

https://journals.lww.com/md-journal/fulltext/2023/08250/safety_and_efficacy_of_5_aminolevulinic_acid.41.aspx

5-ALA is a naturally occurring amino acid that is produced in the cells of humans, animals, and plants. It is also found in many foods as one of the amino acids that we consume daily. Furthermore, because of its high safety and functionality, it has already been utilized in various healthcare products for over 10 years.

Professor Kiyoshi Kita, Dean of the Nagasaki University School of Tropical Medicine and Global Health along with his colleagues at NPJ have been focusing on 5-ALA’s potential as a treatment for malaria. Since 5-ALA shows great potential for inhibiting a wide range of

infectious diseases, both Nagasaki University, with its long history of research in the field of tropical infectious diseases, and NPJ are extensively investigating the potential effects of 5-ALA on as many tropical diseases as possible.

This clinical study was conceptualized and conducted by Professor Koichi Izumikawa, Department of Infectious Diseases, Nagasaki University Graduate School of Biomedical Sciences / Infection Control and Education Center, Nagasaki University Hospital, and Associate Professor Takeshi Tanaka, Infection Control and Education Center, Nagasaki University Hospital. The research plan for the clinical study on 5-ALA administration to patients with COVID-19 infections was approved by the Nagasaki University Accredited Clinical Research Review Ethics Committee on October 28, 2020, and the study was then initiated. This was a multicenter study conducted in collaboration with eight Japanese hospitals.

[Summary of Research Abstract]

- Study Design:

5-ALA is a naturally occurring amino acid that is marketed alongside sodium ferrous citrate (SFC) as a functional food. It was demonstrated to block severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) proliferation in vitro and exhibits anti-inflammatory effects in both humans and animals.

In this phase II open-label, prospective, parallel-group, randomized study, we aimed to evaluate the safety and efficacy of 5-ALA on patients with mild-to-moderate COVID-19 infections.

- Methods:

In this clinical study, patients with mild-to-moderate SARS-CoV-2 infections were randomly chosen to either receive 5-ALA/SFC administration for 14 days, or to be part of the control group. The administration group first received 5-ALA/SFC (250 / 145mg) orally thrice daily for 7 days, and then 5-ALA/SFC (150 / 87mg) orally thrice daily for the following 7 days. The primary endpoints were changes in SARS-CoV-2 viral load, clinical symptom scores, and the safety of 5-ALA/SFC dosages (as measured by adverse events and changes in laboratory values and vital signs).

- Results:

A total of 50 patients were enrolled from eight Japanese hospitals. The change in SARS-CoV-2 viral load from the baseline value was not significantly different between the 5-ALA/SFC (n = 24) and control (n = 26) groups.

While the duration needed for symptoms to improve was shorter for the 5-ALA/SFC group than in the control group, the difference was not significant. The 5-ALA/SFC group exhibited faster improvement rates in terms of ‘dysgeusia’, ‘dysosmia’, and ‘anorexia’ than the control group, and by Day 14 the administration group showed higher improvement rates in terms of ‘coughing’, ‘lethargy’, ‘dysgeusia’ and ‘anorexia’. Eight side-effects were observed in the 5-ALA/SFC group from Day 1. Side-effects occurred for 25% of patients receiving more than 450mg / day in the first phase, and for 6.3% of patients receiving less than 450mg / day in the second phase.

- Conclusion:

Over the 14-day administration period of this study, while 5-ALA/SFC demonstrated a trend towards improving some symptoms in patients with mild-to-moderate COVID-19 infections, there was no observable effects on SARS-CoV-2 viral loads or clinical symptom scores when compared to the control group. In addition, the safety of 5-ALA/SFC for patients was shown to be within acceptable ranges. We believe that further evaluation using a larger sample size or modified methods is warranted.

Please see below for more detailed results : <https://jrct.niph.go.jp/latest-detail/jRCTs071200048>

[Glossary]

*1 Nagasaki University

Nagasaki University is a national university established in 1949. The campus was relocated and integrated in the 1950s and 1960s, and the medical faculties and research institutes (such as the School of Medicine, the School of Dentistry, the Nagasaki University Hospital, and the Institute of Tropical Disease) are now found on the Sakamoto Campus. Nagasaki University has an outstanding track record in the fields of tropical medicine, infectious diseases, and radiological science due to its geographical and historical background, and with its abundant accumulation of research and an unrivaled team of infectious disease researchers, it has become a well-known educational and research base for those studying virulent diseases in Japan and abroad.

<http://www.nagasaki-u.ac.jp/>

*2 neopharma Japan Co., Ltd.

neopharma Japan Co., Ltd is a pharmaceutical company specializing in the research, development, and commercialization of 5-aminolevulinic acid (5-ALA), a natural amino acid. Our Company aims to capitalize on the utility of 5-ALA, which has been confirmed through many years' worth of research on plants, animals, and humans, in a variety of applications in many fields. We are also the only company in the world with facilities capable of 5-ALA mass-production, and we produce the raw materials for 5-ALA foodstuffs under the same quality control as we do for our pharmaceutical products. neopharma Japan is committed to contributing to global healthcare through 5-ALA.

<https://www.neopharmajp.co.jp/>

*3 5-Aminolevulinic Acid (5-ALA)

Human, animals, and plants all maintain their vital functions by producing energy within the organelles called mitochondria inside their cells. 5-aminolevulinic acid (5-ALA) plays an especially significant role in ensuring the functionality of these mitochondria. It is also a very safe amino acid that has been used in health foods, cosmetics, pet supplements, animal feed and fertilizers for over a decade.

<http://5ala-journal.com/>

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